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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/569,556

02/27/2006

Makoto Ogiso

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EXAMINER

COBURN, LESLIE

ART UNIT

PAPER NUMBER

3774

NOTIFICATION DATE

DELIVERY MODE

05/06/2011

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/569,556	Applicant(s) OGISO, MAKOTO	
	Examiner LESLIE COBURN	Art Unit 3774	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,9-19 and 22-28 is/are pending in the application.
- 4a) Of the above claim(s) 3,4,11-13,15,16,23 and 24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 5-6, 9-10, 14, 17-19, 22, 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/25/2011</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Reopening of Prosecution After Appeal

1. In view of the appeal brief filed on 12/20/2010, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/DAVID ISABELLA/

Supervisory Patent Examiner, Art Unit 3774

Status of the Claims

2. The Claims 1-6, 9-19, and 22-28 are pending. Claims 3-4, 11-13, 15-16, and 23-24 are withdrawn. Claims 1-2, 5-6, 9-10, 14, 17-19, 22, and 25-28 are rejected.

Response to Arguments

3. Applicant's arguments, see appeal brief, filed 12/20/2010, with respect to the rejection(s) of claim(s) 1, 2, 5, 6, 9, 10, 14, 17-19, 22, and 25-28 under 35 U.S.C. 103(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Boyce, et al (US 5,899,939), Chou (US 2004/0191292), Smith, et al (2004/0253279 A1), Takagi, et al (US 4,654,314), and Levine, et al (US 2003/0220696 A1).

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 9 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, these claims require the fine bone powder to have a diameter less than or equal to 50 microns, while the claims from which they depend require sub-micron particle diameters (less than 1 micron). Claims 9 and 22 claim options that are outside the scope claimed in the claims from which they

Art Unit: 3774

depend, specifically bone powder diameters in the range $1 \text{ micron} \leq \text{diameter} \leq 50$ microns. This contradiction makes these claims indefinite.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 1, 9-10, 14, 17, 22, 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce, et al (Boyce) (US 5,899,939) in view of Chou (US 2004/0191292).

Regarding **Claims 1, 9, 17, and 22**, Boyce teaches **a bone-powder-impregnated, porous structure comprising a porous matrix** (column 4, lines 53-56) **made of a biocompatible material** (demineralized bone, column 3, line 11-40)

Art Unit: 3774

impregnated with fine bone powder (column 4, lines 57-61 and column 4, lines 63-65 with bone powder found in column 5, lines 15-16) **obtained by pulverizing living bones and/or teeth** (demineralized bone, column 5, lines 15-16).

Note: It is the Examiner's position that the process of demineralization results in a similar structured bone powder as results from the process of pulverizing. Further, the Examiner notes that the Applicant provides both pulverizing and demineralization as alternative process to produce bone powder, but does not distinguish between any specific characteristics of these methods in the disclosed Specification.

Boyce discloses the invention substantially as claimed but fails to teach that **the fine bone powder comprises sub-micron particles**.

Chou teaches the use of sub-micron particles impregnated within a polymer matrix for a bone scaffold ([0024]). The average diameter of these particles must be 50 microns or less.

Boyce and Chou are concerned with the same field of endeavor, namely porous bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the bone powder size of Boyce to have a sub-micron size as taught by Chou in order to embed the particles evenly within the matrix.

Note: It is the Examiner's position that a surface-roughened structure is a porous structure as the process of surface-roughening is one way to produce a porous surface.

Art Unit: 3774

Regarding Claims **10, 14, and 25**, Boyce teaches an implant where the entire structure is porous (made of layers of porous material, e.g. column 6, lines 1-6). Further Boyce teaches the porous structure makes a femur, which is a limb (column 6, lines 8-13).

9. Claims 1-2, 5-6, and 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith, et al (Smith) (2004/0253279 A1) in view of Boyce, et al (Boyce) (US 5,899,939) and further in view of Chou (US 2004/0191292).

Smith teaches **an impregnated, porous structure comprising a porous matrix** (porous article, [0017]) **made of a biocompatible material** (ceramic, [0043]; hydroxyapatite, [0044]).

Smith discloses the invention substantially as claimed but fails to teach the porous structure **impregnated with fine bone powder obtained by pulverizing living bones and/or teeth**.

Note: The Examiner's positions on demineralization versus pulverization and on surface-roughened structure are discussed supra.

Boyce teaches a porous bone scaffold **impregnated with fine bone powder** (column 4, lines 57-61 and column 4, lines 63-65 with bone powder found in column 5, lines 15-16) **obtained by pulverizing living bones and/or teeth** (demineralized bone, column 5, lines 15-16).

Boyce and Smith are concerned with the same field of endeavor, namely bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the impregnating powder of Smith by incorporating the demineralized bone of Boyce in order to promote and/or accelerate new bone growth.

The combination of Smith and Boyce discloses the invention substantially as claimed but fails to teach that **the fine bone powder comprises sub-micron particles**.

Chou teaches the use of sub-micron particles impregnated within a polymer matrix for a bone scaffold ([0024]).

Chou and the combination of Smith and Boyce are concerned with the same field of endeavor, namely porous bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the bone powder size of the combination of Smith and Boyce to have a sub-micron size as taught by Chou in order to embed the particles evenly within the matrix.

Regarding **Claims 2 and 18**, Smith teaches pore (or recess) sizes from 15-50 microns ([0043]). Further, Smith teaches at least 1 pore per area of 50 microns x 50 microns discussed as follows. Smith teaches a porosity of 20-95% ([0023]) and a uniform distribution of pores ([0047]). For example, at a porosity of 95% and a pore size of 15 microns, pores cover 95% of the surface area (or $0.95 \times (50 \times 50) = 2375$ microns squared). Each pore (being approximately spherical with a circular cross section, e.g.

Art Unit: 3774

Figure 2) would have a surface area of ($\pi \cdot 7.5 \cdot 7.5 = 177$ microns squared) meaning that there are approximately 13 pores per area of 50 microns x 50 microns.

Regarding **Claims 5-6 and 19**, Smith teaches a porous matrix made of a ceramic ([0043]) and more specifically the calcium phosphate hydroxyapatite ([0044]).

10. **Claim 26** is rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce, et al (Boyce) (US 5,899,939) in view of Chou (US 2004/0191292) as discussed supra and further in view of Takagi, et al (Takagi) (US 4,654,314).

Although Boyce teaches that Bone-derived implants of any desirable size and/or configuration can be provided (column 4, lines 45-46), Boyce fails to teach specifically a dental root.

The combination of Boyce and Chou discloses the invention substantially as claimed but fails to teach porous structure to be used as a dental root.

Takagi teaches a porous ceramic material used to as a material for a dental root (abstract).

Takagi and the combination of Boyce and Chou are concerned with the same field of endeavor, namely porous bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the final product of the combination of Boyce and Chou to take the form of a dental root as taught by Takagi in order to provide replacement prosthesis.

Art Unit: 3774

11. **Claims 27 and 28** are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyce, et al (Boyce) (US 5,899,939) in view of Chou (US 2004/0191292) as discussed supra and further in view of Levine, et al (Levine) (US 2003/0220696 A1).

The combination of Boyce and Chou discloses the invention substantially as claimed but fails to teach an autologous bone powder source.

Levine teaches a bone scaffold where the tissues used are autologous ([0024]).

Levine and the combination of Boyce and Chou are concerned with the same field of endeavor, namely porous bone matrices.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the source tissue of the combination of Boyce and Chou by incorporating an autologous tissue source as taught by Levine in order to produce a graft made from the recipient's own cells.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE COBURN whose telephone number is (571)270-7044. The examiner can normally be reached on M-Th 8:00 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. C./
Examiner, Art Unit 3774
4/29/2011

/DAVID ISABELLA/
Supervisory Patent Examiner, Art
Unit 3774